

steps. Unless otherwise recited, the claimed method steps can be performed by any structure or person (e.g., a controller/microprocessor, a doctor or medical technician, etc.). These options make claim 1 broad, not indefinite. The Office Action's recognition that various claimed steps could be performed by "a controller/microprocessor or mentally by a doctor or other medical technician present" confirms both the breadth and definiteness of the claim. *See Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) ("The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles... Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite.") (quoted at MPEP 2173.02). Applicants therefore respectfully request the withdrawal of this indefiniteness rejection.

Obviousness Rejection Over Edgar

Claims 21 and 23-25 were rejected under 35 U.S.C. § 103(a) as obvious over Edgar (U.S. Patent No. 4,677,975). Applicants respectfully traverse this rejection as applied to independent claim 21 because at least two recitations in claim 21 are totally missing from Edgar.

First, claim 21 recites, among other things, that "the controller is configured to ... detect, via the airflow sensor, a time the person takes to stop inhaling after being signaled." Edgar discloses the ceasing of inhale signals to the patient (alleged by the Office Action to be the recited "signal to the person to cease inhalation"). *See* Edgar, col. 3, lines 13-14 ("the inhale signals at 24 are turned off"). Edgar also discloses sensing the start of exhalation (alleged by the Office Action to be the detection of the stop of inhalation). *See* Edgar, col. 3, line 17 ("the start of exhalation is detected"). However, Edgar does not disclose or suggest detecting a length of time between those two events, i.e., "a time the person takes to stop inhaling after being signaled," as recited in claim 21. Such a time is irrelevant to the operation of Edgar's device. Moreover, Edgar never recognizes any reason to detect such a time, and there was no other obvious reason to have detected a "time the person takes to stop inhaling after being signaled," as recited in claim 21.

Second, claim 21 recites, among other things, that “the controller is configured to ... adjust the pre-set period of time for subsequent inhalations depending on the detected time the person takes to stop inhaling after being signaled.” Because Edgar does not even detect this “detected time,” as explained above, Edgar does not disclose adjustment of the pre-set period of time based on a non-disclosed, non-obvious “detected time.” Indeed, Edgar does not disclose any ability whatsoever to adjust the pre-set period of time, much less a controller that adjusts such a pre-set period of time “depending on the detected time the person takes to stop inhaling after being signaled,” as recited in claim 21. Nor would it have been obvious to modify Edgar’s controller to “adjust the pre-set period of time for subsequent inhalations depending on the detected time the person takes to stop inhaling after being signaled,” as recited in claim 21, because there was no obvious reason to have done so.

The Office Action responds to the above argument by asserting that Edgar’s apparatus is “capable of adjusting a pre-set inhalation time.” 12/22/09 Office Action, p. 9, ¶ 10. Applicants specifically traverse this assertion because Edgar includes no such disclosure. The Office Action’s cited passage from Edgar merely states that “a compressed air nebulizer is used, which is able to be switched on and off and the intermittent nature of the operation allows selection of the running period to achieve a desired result.” Edgar, col. 3, lines 24-27. The selection of a “running period” involves the total running time of the apparatus for a desired dose, which includes numerous breaths. *See* Edgar, col. 2, lines 44-65. Such a running period has nothing to do with a “pre-set inhalation time,” which involves a single inhalation.

Furthermore, even if Edgar’s adjustment of the “running period” were incorrectly deemed an adjustment of the “pre-set inhalation time,” such adjustment still would not “depend[] on the detected time the person takes to stop inhaling after being signaled,” as recited in claim 21.

For at least these reasons, Applicants respectfully request the withdrawal of the obviousness rejection of claim 21, as well as its dependent claims, which are allowable at least because they depend from patentable claim 21.

Obviousness Rejection Over Schuster in view of Mishelevich and Crockford

Claims 1-12, 18-20, and 27 were rejected under 35 U.S.C. § 103(a) as obvious over Schuster (U.S. Patent No. 5,906,202) in view of Mishelevich (U.S. Patent No. 5,363,842) and Crockford (U.S. Patent Application Publication No. 2003/0205229). Applicants respectfully traverse this rejection as applied to independent claim 1 for the following reasons.

First, claim 1 recites, among other things, “detecting a time the person takes to stop inhaling after being signaled.” None of the cited references, either individually or in combination, disclose such a combination of recitations. Although Schuster discloses “prompt[ing] the patient to stop the inhalation,” Schuster does not disclose the detection of how long it takes the patient to comply. Schuster, col. 2, line 63. Mishelevich and Crockford are similarly deficient.

The Office Action responds to this argument by asserting that:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Schuster to include the steps of detecting a pre-set time duration of inhalation and comparison to target envelope as taught by Mishelevich in order to ascertain a more accurate description of a patient’s breathing pattern.

12/22/09 Office Action, p. 4 (underlining added). Even if true, the Office Action admits that the resulting combination would merely measure a “pre-set time duration of inhalation” as a whole. Measurement of the duration of the entire inhalation is not a measurement of “a time the person takes to stop inhaling after being signaled” to stop inhalation, as recited in claim 1.

The Office Action next asserts that “[t]he modified Schuster’s device also discloses the ability of the microprocessor to detect a time the person takes to stop inhaling after being signaled (col. 13, ln. 34-36).” 12/22/09 Office Action, p. 4 Applicants respectfully traverse this assertion because the cited passage includes no such teaching. Rather, the recited passage merely states that “[t]he recorded information is analyzed by the microprocessor in order to deduce the timing and volume of aerosol and particle free air to be released into the patient’s inspiratory cycle.” Schuster, col. 13, lines 34-36. This passage does not disclose or otherwise render obvious “detecting a time the person takes to stop inhaling after being signaled,” as recited in claim 1.

The Office Action similarly responds to Applicants' above argument by asserting that the proposed combination "contains structure such that it is capable of detecting the time as claimed." 12/22/09 Office Action, p. 10 (underlining added); *see also id.* at p. 4 ("[t]he modified Schuster's device also discloses the ability of the microprocessor to detect a time the person takes to stop inhaling after being signaled (col. 13, ln. 34-36).") (underlining added). Even if correct, the ability/capability of a structure to be used in a manner recited in method claim 1 falls far short of a disclosure of such a prior art structure actually being used in the claimed manner. The Office Action therefore fails to provide a *prima facie* obviousness rejection because the Office Action has not alleged, must less demonstrated that it would have been obvious to use the proposed combined structure to "detect[] a time the person takes to stop inhaling after being signaled," as recited in method claim 1. *See KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727, 1731, 82 USPQ.2d 1385, 1396 (2007) (stating that it is necessary to determine whether there was an "apparent reason" to combine the known elements in the claimed manner); *see also id.* ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.").

Second, claim 1 recites, among other things, "adjusting the pre-set period of time for subsequent inhalations." The Office Action concedes that Schuster lacks such a teaching. The Office Action similarly concedes that modifying Schuster in view of Mishelevich likewise lacks such a teaching because Mishelevich merely discloses "direct[ing] the patient to change breathing pattern to match the pre-set time period instead of changing the pre-set time period." 12/22/09 Office Action, p. 4. The Office Action asserts that Crockford would have made it obvious to have adjusted the pre-set period of time "in order to accommodate to a patient's breathing pattern who may have respiratory problems and cannot change their breathing pattern" based on Crockford's alleged disclosure of "adjust[ing] subsequent breathing patterns to match the patient's needs (Crockford para. 0056 ln. 9-15)." 12/22/09 Office Action, pp. 4-5. To the contrary, Crockford has no such teaching. Crockford does not teach adjusting the patient's breathing pattern at all, and is merely directed toward adjusting internal workings of the drug

delivery device itself. The cited passage from Crockford merely discloses changing the timing of atomization within the device so as to occur “during a part of the inhalation of the patient.” Crockford, ¶ [0056]. Such internal workings of Crockford’s device have nothing to do with changes to how Crockford’s device instructs the patient to breath. Thus, Crockford does not make it obvious to “adjust[] the pre-set period of time for subsequent inhalations,” wherein the pre-set period is used to “signal[] to the person to cease inhalation,” as recited in claim 1.

The Office Action responds by asserting that the proposed combination of prior art is “capable of adjusting based on the time periods.” 12/22/09 Office Action, p. 10 (underlining added). Again, the ability/capability of a structure to be used in a manner recited in method claim 1 is not the same as a disclosure of such a prior art structure actually being so used. The Office Action therefore fails to provide a *prima facie* obviousness rejection because the Office Action has not even alleged, must less demonstrated that it would have been obvious to use the proposed combined structure to “adjust[] the pre-set period of time for subsequent inhalations,” as recited in method claim 1.

Third, claim 1 recites, among other things, “adjusting the pre-set period of time for subsequent inhalations depending on the time the person takes to stop inhaling after being signaled.” None of the cited references, nor their combination, disclose such a combination of recitations because, as explained above, they do not even render obvious the detection of such a “time the person takes to stop inhaling after being signaled.” Accordingly, the cited references cannot render obvious using such a non-disclosed, non-obvious “time the person takes to stop inhaling after being signaled” as the basis for “adjusting the pre-set period of time,” as recited in claim 1.

The Office Action asserts that the combination would render it obvious “to adjust[] the pre-set time...in order to accommodate to a patient’s breathing pattern who may have respiratory problems and cannot change their breathing pattern.” 12/22/09 Office Action at 4-5. Even if such an assertion were correct (Applicants dispute this as explained above), Applicants specifically traverse the Office Action’s further assertion that such accommodation for the patient’s respiratory problems/breathing cycle “would depend on the time the person takes to

stop inhaling after the signaled [sic] to stop as comparison to target envelopes.” 12/22/09 Office Action, p. 5. Quite to the contrary, adjustment to accommodate for the specific breathing cycle of a patient does not necessarily or obviously depend on the time the person takes to stop inhaling after any signal to stop inhalation is given. A patient’s respiratory-problem-based breathing cycle has nothing to do with a lag between when the patient is signaled to stop inhalation and when the patient actually does so. Thus, none of the references, nor their combination disclose or otherwise render it obvious to adjust the pre-set time based on a patient’s compliance lag, i.e., “the time the person takes to stop inhaling after being signaled.”

For at least these reasons, Applicants respectfully request the withdrawal of this obviousness rejection of claim 1, as well as its dependent claims, which are allowable at least because they depend from patentable claim 1.

Obviousness Rejections of Claim 1’s Dependent Claims

Claim 13 was rejected under 35 U.S.C. § 103(a) as obvious over Schuster in view of Mishelevich, Crockford, and Krumbiegel (U.S. Patent No. 5,928,156). Claims 14-17 were rejected under 35 U.S.C. § 103(a) as obvious over Schuster in view of Mishelevich, Crockford, Krumbiegel, and Strom (U.S. Patent No. 6,240,920). Applicants respectfully traverse these rejections at least because these claims depend, either directly or indirectly, from claim 1, and claim 1 is patentable over Schuster in view of Mishelevich and Crockford as explained above. Krumbiegel and Strom do not cure any of those deficiencies with respect to claim 1. Applicants therefore respectfully request the withdrawal of this obviousness rejection.

Obviousness Rejection Of Claim 21’s Dependent Claims

Claim 22 was rejected under 35 U.S.C. § 103(a) as obvious over Edgar in view of Reinhold (U.S. Patent No. 7,073,499). Claim 26 was rejected under 35 U.S.C. § 103(a) as obvious over Edgar in view of Schuster. Applicants respectfully traverse this rejection at least because these claims depend from claim 21, and claim 21 is patentable over Edgar as explained above. Reinhold and Schuster do not cure any of Edgar’s deficiencies with respect to claim 21. Applicants therefore respectfully request the withdrawal of this obviousness rejection.

Conclusion

To the extent that Applicants have not separately addressed each rejection of each dependent claim, this is not to be construed as an admission of the correctness of that rejection. Rather, Applicants believe that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of one or more of the dependent claims need not be addressed at this time. Applicants reserve the right to address the rejection of any dependent claim at a later time should that become warranted.

Applicants submit that the present application is in condition for allowance, and earnestly solicit an early notification to that effect.

Should there be any questions or concerns regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Please charge any fees associated with the submission of this paper to Deposit Account Number 50-0558. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

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